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(54) MEDICAL APPARATUS REMOTE CONTROL AND METHOD

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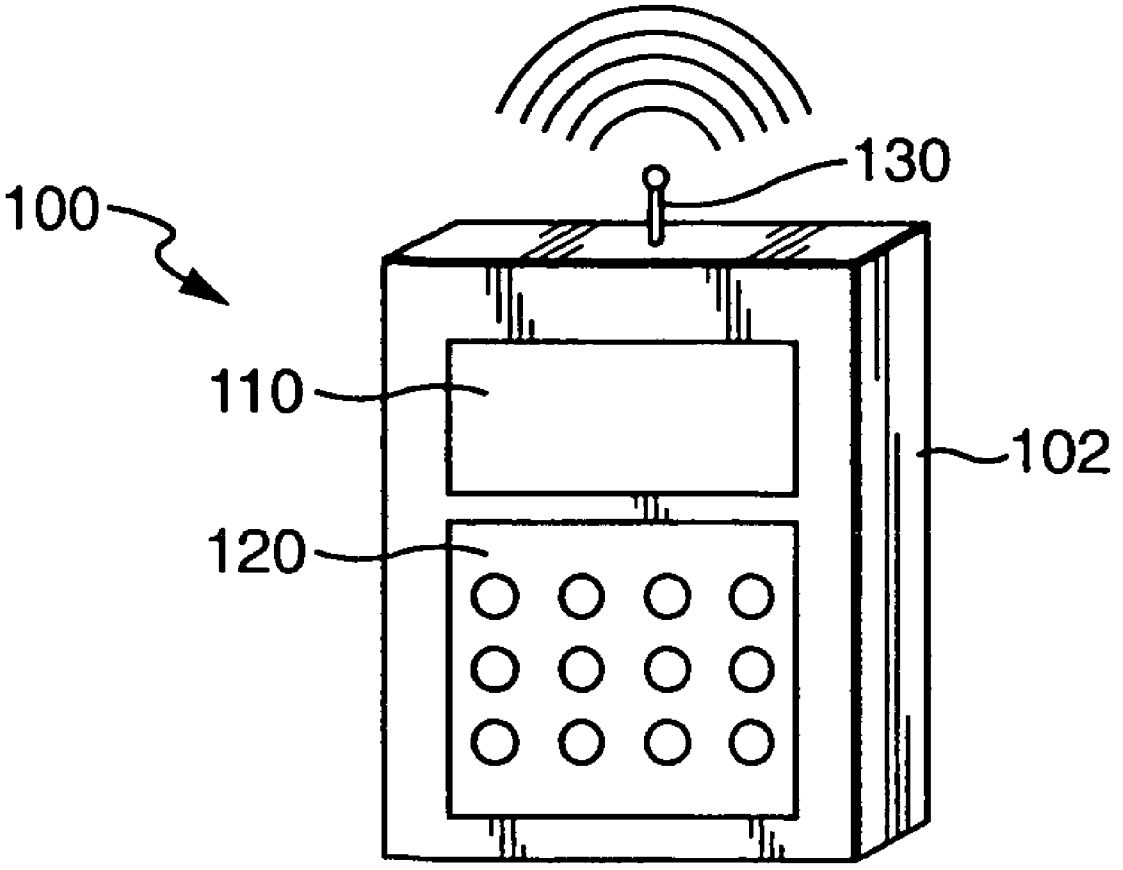
(57) **ABSTRACT**

A system for providing medical treatment to a patient, including a medical treatment apparatus and a remote control device. The medical treatment apparatus has a local processor, and a local communication element connected to the local processor, while the remote control device includes a remote processor, user interface components connected to the remote processor, and a remote communication element connected to the remote processor and adapted to communicate with the local communication element of the medical treatment apparatus in a wireless manner such that information can be transferred between the local processor and the remote processor. The remote control device also includes at least two separate power supplies connected to the remote processor.



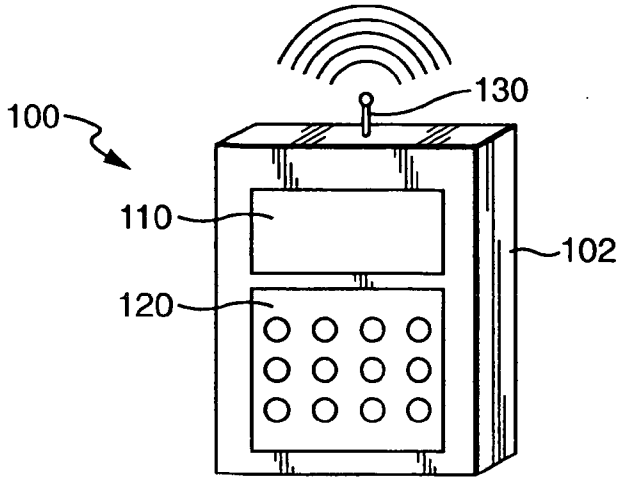

100
130
110
102
120

FIG. 1

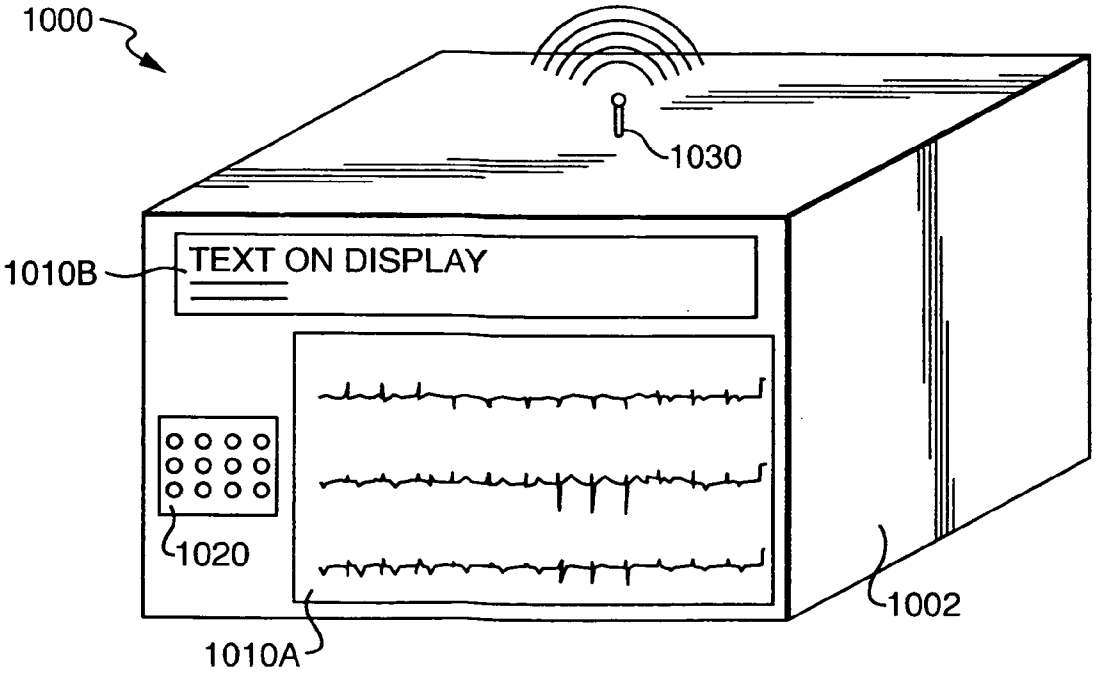

1000
1030
1010B
TEXT ON DISPLAY
1020
1002
1010A

FIG. 1A

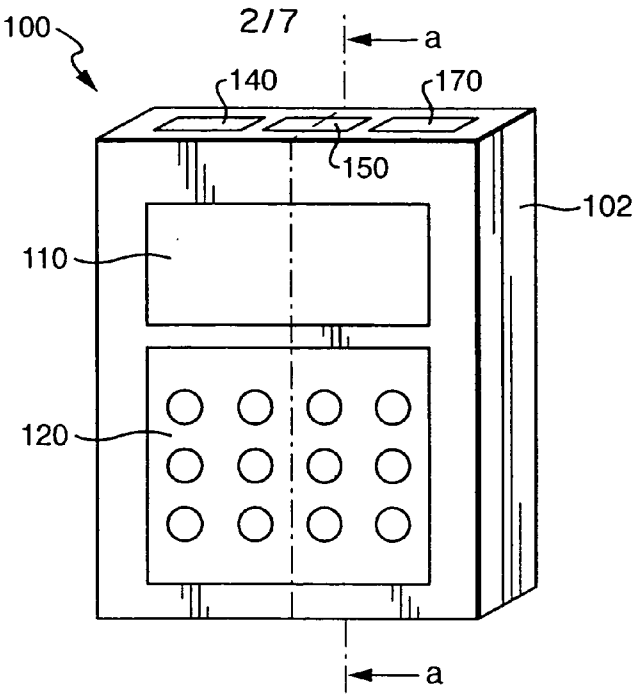


FIG. 2

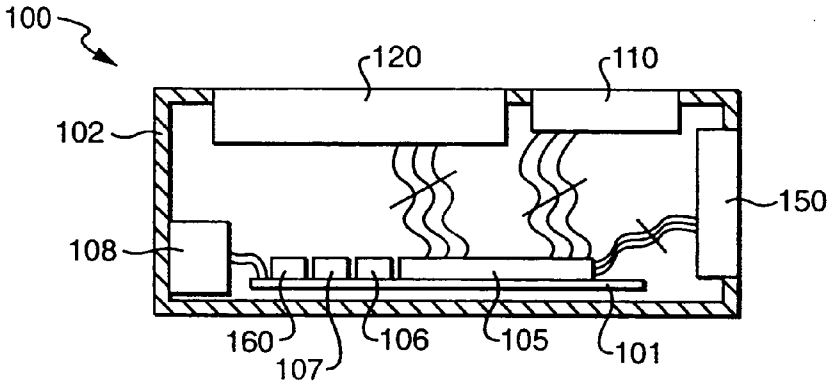


FIG. 2A

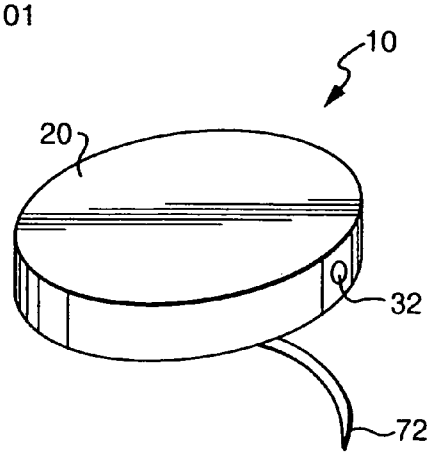


FIG. 2B

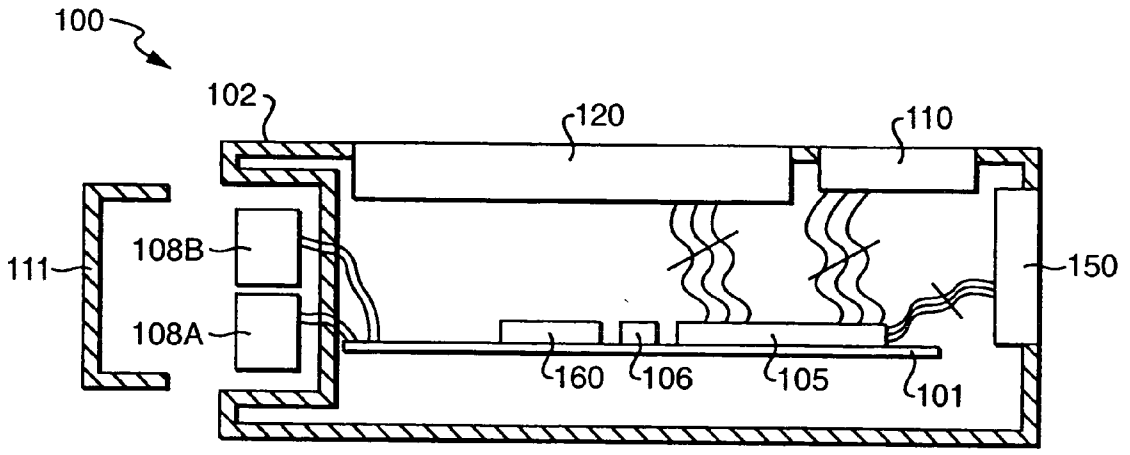

100
102
120
110
111
108B
108A
150
160
106
105
101

FIG. 3

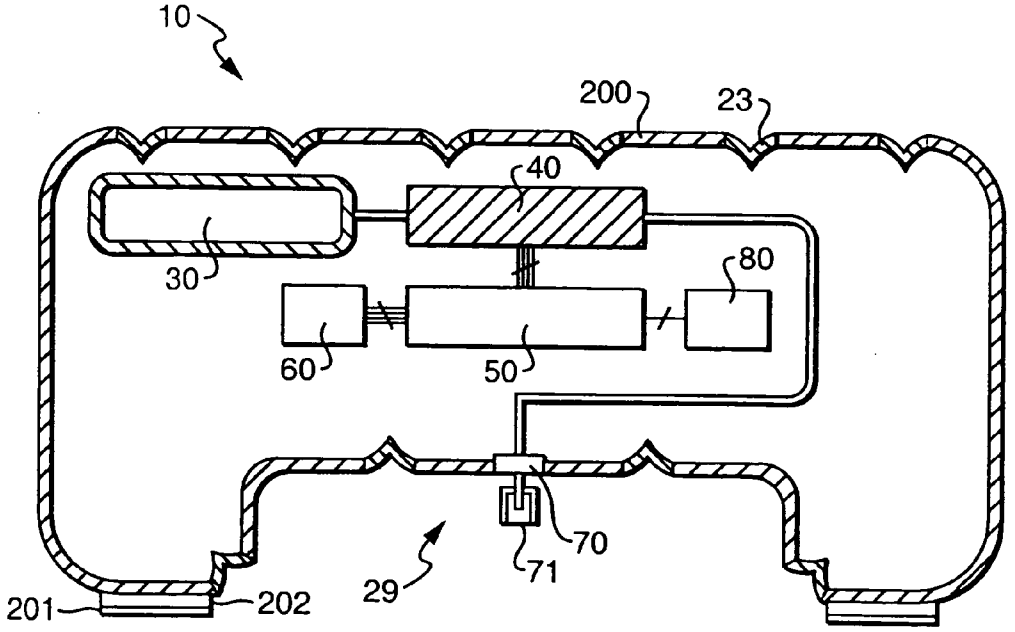

10
200
23
40
30
80
60
50
70
71
29
201
202

FIG. 3A

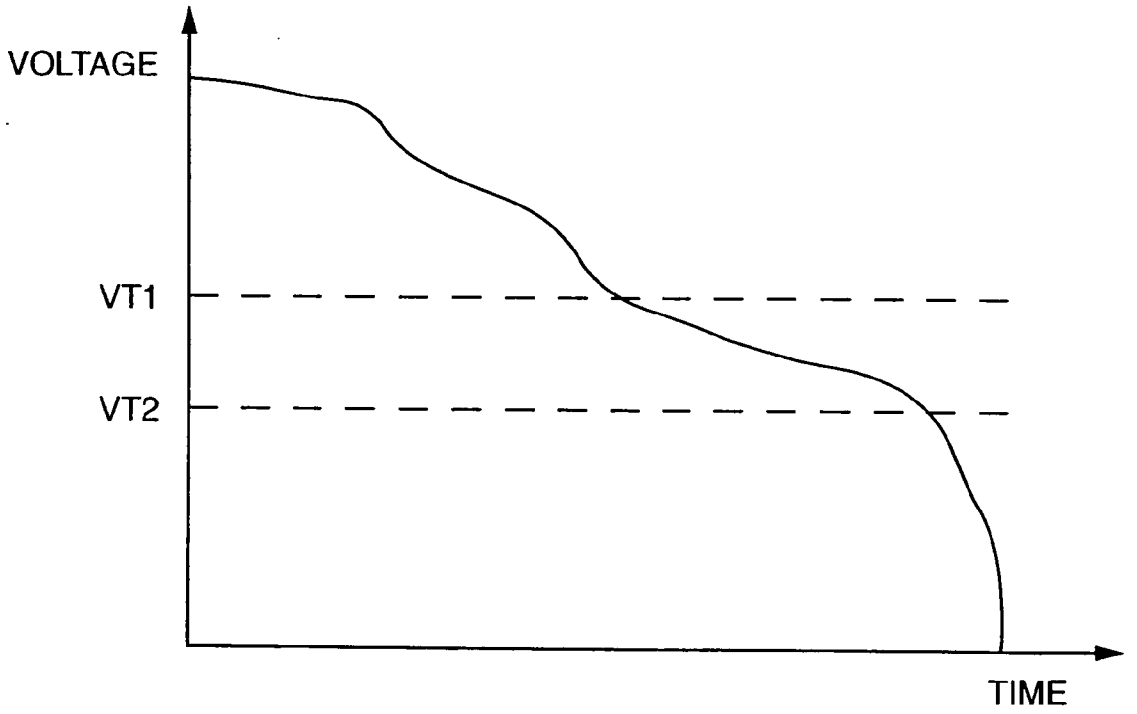


FIG. 4

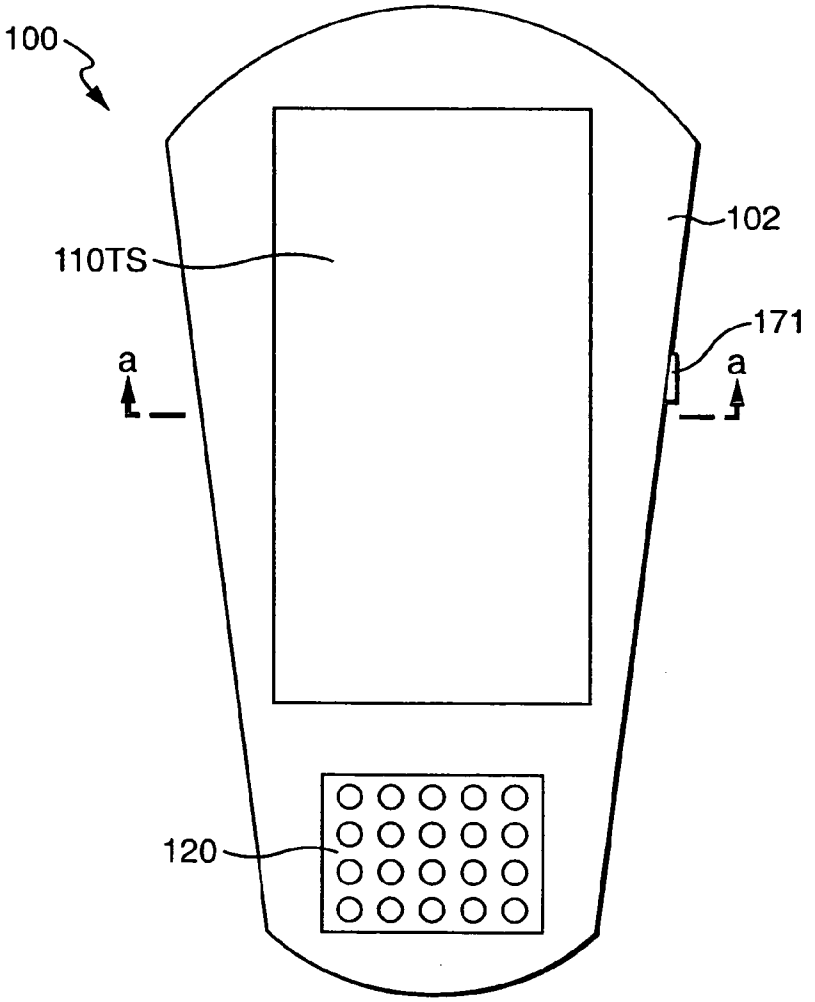

100
102
110TS
171
a
a
120

FIG. 5

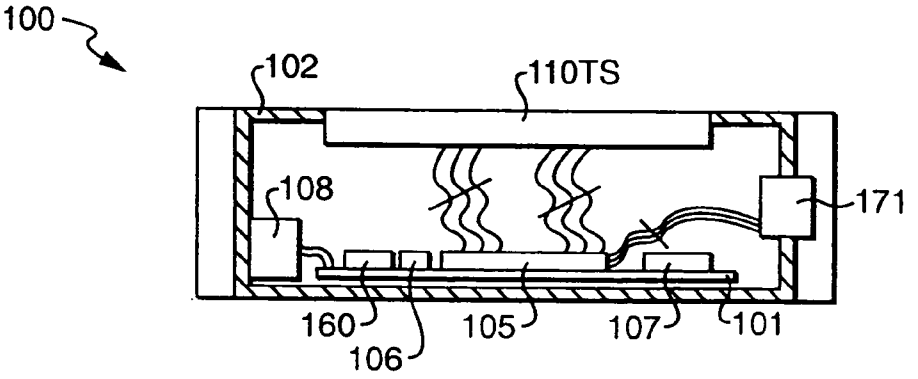

100
102
110TS
108
171
160
106
105
107
101

FIG. 5A

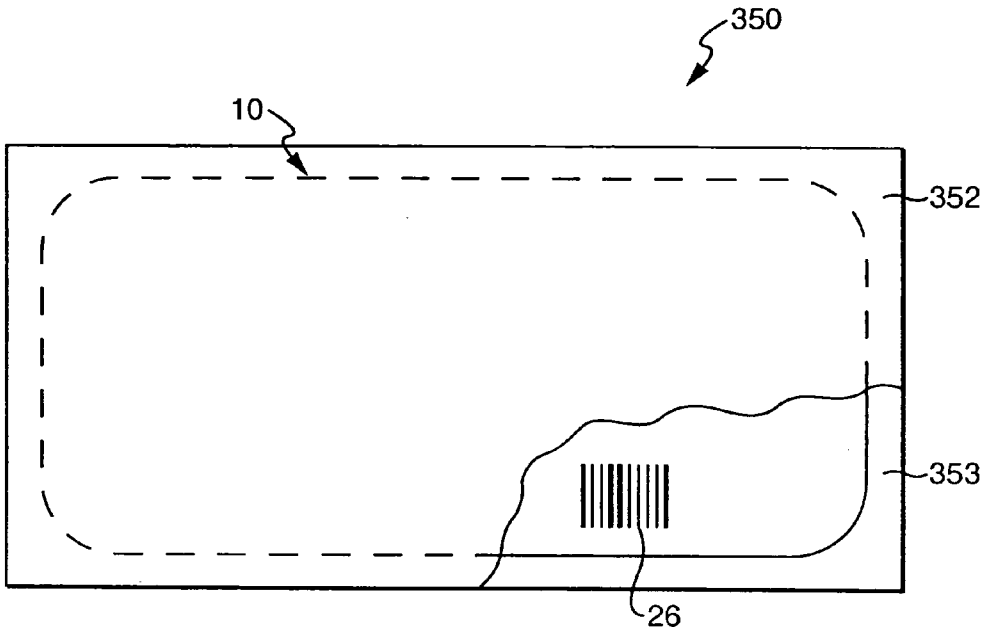


FIG. 6

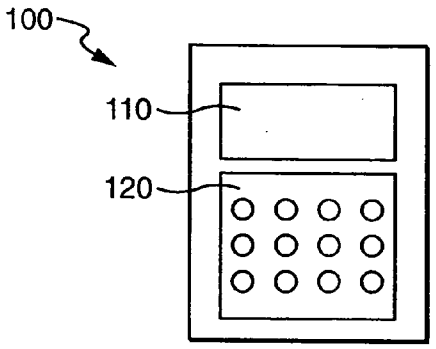


FIG. 6A

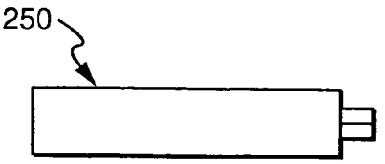


FIG. 6B

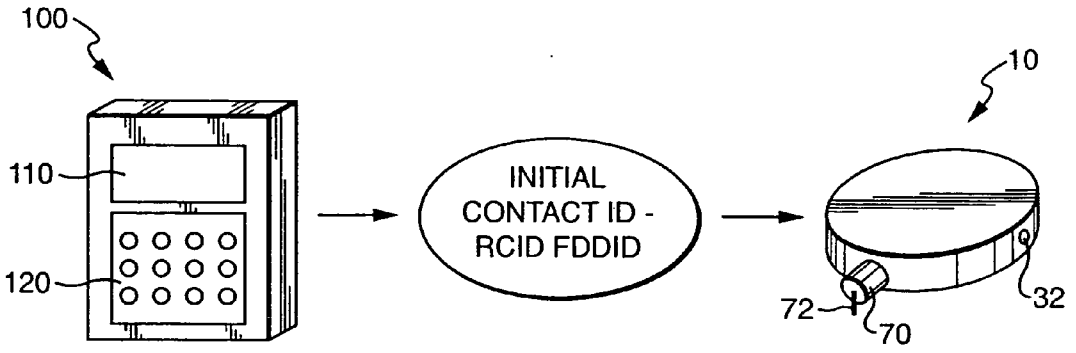


FIG. 7

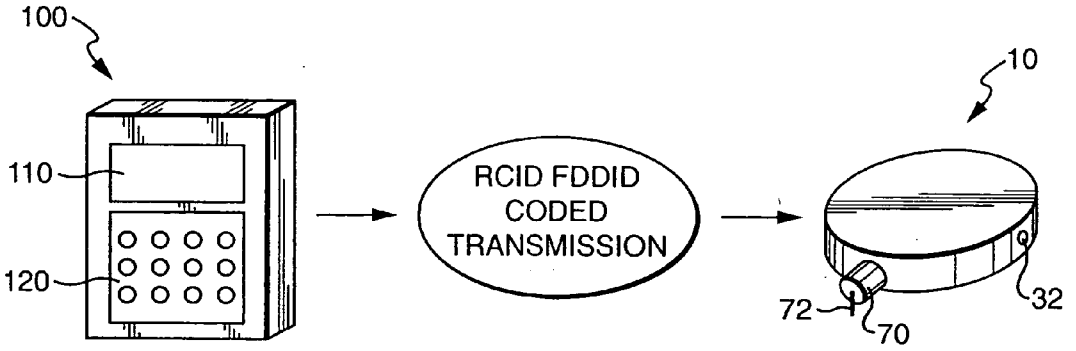


FIG. 7A

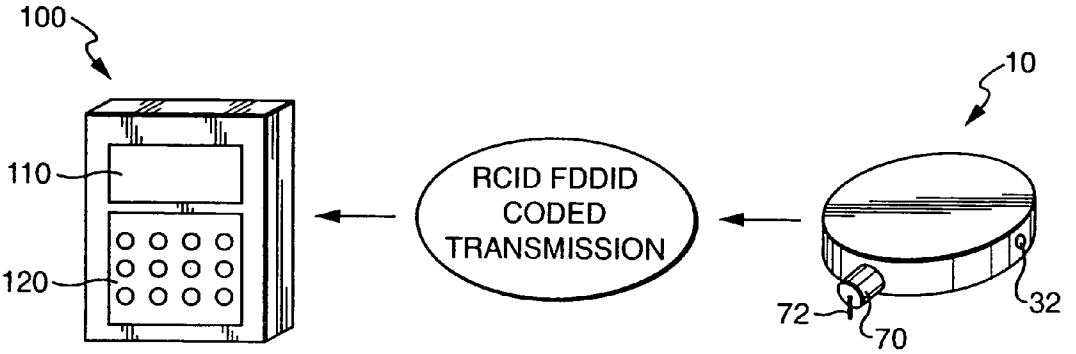


FIG. 7B

MEDICAL APPARATUS REMOTE CONTROL AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to provisional U.S. patent application serial No. 60/257,756, filed on Dec. 21, 2000, which is assigned to the assignee of the present application and incorporated herein by reference. The present application is related to U.S. patent application Ser. No. 09/943,992, filed on Aug. 31, 2001, which is assigned to the assignee of the present application and incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to handheld devices that perform multiple functions, and more particularly to a handheld device for remotely controlling one or more medical apparatuses in addition to performing other functions for a user.

BACKGROUND OF THE INVENTION

[0003] Today, there are various handheld electronic devices that are routinely carried by a large portion of the population on a daily basis. Examples of these devices include cellular telephones such as those offered by Nokia or Motorola, personal digital assistants (PDA's) such as those offered by Palm, Inc., handheld electronic games such as the Lunker Bass Fishing game by Radica, garage door openers, and various other handheld electronic devices that perform specific functions for a user. In recent years, technological advances have allowed significant enhancements in such handheld electronic devices including reduced size and weight, longer battery life, simplified user interfaces, and other additional new features and improvements. For example, the addition of a touch screen panel, such as that incorporated into the Palm Pilot personal digital assistant, allows simple menu driven access to personal calendars, address books, to-do lists and email.

[0004] Other handheld electronic devices include remote control devices such as those commonly supplied with televisions, video cassette recorders (VCR's), and DVD players. Using wireless communication, such as radio frequency, infrared or ultrasound, these remote control devices allow a user to control separate electronic equipment without having to be in proximity to or otherwise have access to the controls of the separate electronic equipment.

[0005] Various medical apparatus can be controlled with a remote control device as well. Examples of these devices include x-ray machines, operating tables, diagnostic monitors, and drug infusion devices. The medical apparatus remote control devices provide similar advantages to television or VCR remote control devices, obviating the need for a user to be proximal to or have access to the controls of the medical apparatus.

[0006] As handheld electronic devices and remote control devices have become widespread in their use, it has become desirable to combine multiple products or functions into single devices. Such devices having multiple functions do exist, but usually the particular grouping of functions are related, such as the "universal remotes" available for televisions, VCRs, and other home audiovisual equipment remote control devices. In U.S. Pat. No. 4,855,746, for example, Stacy shows a multi-device remote control with an array of keys that are exposed in pre-selected groups by moving a slidable cover. A position of the slidable cover determines which device the remote control device will control and the type of coded control signals that the remote control device will transmit. Other examples of devices having multiple functions include some recent cellular telephones, which have been manufactured with personal computer functions, electronic address and calendar functions, and built-in internet access.

[0007] User controlled ambulatory infusion devices can be an ideal use for a remote control. Ambulatory infusion pumps have been developed for delivering liquid medicaments to a patient. These infusion devices have the ability to offer sophisticated fluid delivery profiles accomplishing bolus requirements, continuous infusion and variable flow rate delivery, which can result in better efficacy of the drug and therapy and less toxicity to a patient's system. An example of a use of an ambulatory infusion pump is for continuous subcutaneous infusion of insulin to diabetic patients. Many diabetics require insulin intake to treat their disease, and continuous subcutaneous infusion of insulin from an infusion pump has been shown in numerous studies to greatly improve the immediate and long term health conditions of those patients. These pumps can deliver insulin on a continuous basal basis as well as a bolus basis as shown, for example, in U.S. Pat. No. 4,498,843 to Schneider et al.

[0008] User controlled ambulatory infusion devices are an ideal use for a remote control since the infusion devices may be located out of reach of a patient, or may be discreetly located beneath clothing or in a carrying pouch. Since the diabetic patient utilizing an ambulatory infusion pump may wish to place the device beneath their clothing, for added comfort and or for privacy, a remote control device is appropriate to adjust various parameters associated with the infusion pump, or simply to review pump status or other pump information. These patients may also carry a glucose measuring device such as a glucometer as well as a cellular phone, pager, PDA or other handheld electronic device not directly associates with the treatment of their health condition. Ambulating with multiple handheld devices such as these can be fraught with issues not the least of which is confusion, and the increased probability of losing one of the devices.

[0009] Certain ambulatory infusion devices may be designed to be of limited life or even disposable. For example, U.S. patent application Ser. No. 09/943,992, filed on Aug. 31, 2001, which is assigned to the assignee of the present application and incorporated herein by reference discloses a remotely controlled, disposable infusion pump. In such cases, it would be desirable to provided a non-disposable remote control device that can be used to control successive disposable pumps.

[0010] If a handheld electronic device is to be used for controlling a medical apparatus, such as an infusion pump, certain prioritization of performance may be desired. One such prioritization, for example, relates to power consumption. As most of today's handheld devices are powered by a replaceable or rechargeable battery, it may be desirable to regulate power consumption and low battery conditions in a

specialized manner. In U.S. Pat. No. 4,514,732, for example, Hayes shows power conservation methods for particular commands of a remote control for electronic audiovisual equipment. When a user continually presses a key on the remote control, such as to decrease volume, the remote control is programmed to send a single command signal to the equipment to start decreasing volume when the user initially presses the button, and to send a single command signal to stop decreasing volume when the button is released. Hayes' method avoids sending a continuous stream of signals to dictate the volume decrease in the equipment, thus reducing the power consumption of the remote control.

[0011] Some electronic handheld devices and remote controls include low battery warnings via an audible alert, screen message or other visual low battery indicator. Often, these devices are used until the batteries contain insufficient energy to power the device at which time the batteries are replaced or recharged. However, for controlling medical treatment apparatus, such down time due to lack of new batteries could be very undesirable.

[0012] Accordingly, there continues to be a need for remote control devices which can be used with medical treatment apparatus, such as disposable infusion pumps, as well as other functions. The additional functions may be related to the therapy or medical treatment apparatus itself, such as a blood glucose measuring function for the diabetic patient controlling an ambulatory insulin pump. The additional functions may be unrelated, such as PDA, cellular telephone, or game functions. Desired remote control devices, therefore, will obviate the need for a user to carry multiple handheld devices. Preferably, the remote control devices will include power consumption regulations that prioritize power delivery for the medical controlling functions of the devices. In addition, the remote control devices will preferably include battery monitoring which substantially avoids a total loss of power for the medical controlling function. Moreover, such remote control devices will be adapted for use with multiple medical treatment apparatus, such as successive disposable infusion pumps.

SUMMARY OF THE INVENTION

[0013] In response, the present invention provides a remote control for a medical treatment apparatus that includes functions in addition to control of the medical apparatus, as desired. According to one exemplary aspect, the multi function medical apparatus remote control device includes power consumption regulations that prioritize power delivery for the medical controlling functions of the devices. According to another exemplary aspect, the multi function medical apparatus remote control device includes battery monitoring which substantially avoids a total loss of power for the medical controlling function. According to an additional exemplary aspect, the multi function medical apparatus remote control device adapted for simultaneously or serial use with multiple medical treatment apparatus, such as successive disposable infusion pumps. Also provided as an aspect of the present invention are methods for assuring proper communication between a remote control device a specific device to be controlled.

[0014] These aspects of the invention together with additional features and advantages thereof may best be understood by reference to the following detailed descriptions and examples taken in connection with the accompanying illustrated drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a perspective view of an exemplary embodiment of a remote control device constructed in accordance with the present invention;

[0016] **FIG. 1***a* is a perspective view of an exemplary embodiment of a medical treatment apparatus constructed in accordance with the present invention;

[0017] **FIG. 2** is a perspective view of another exemplary embodiment of a remote control device constructed in accordance with the present invention;

[0018] **FIG. 2***a* is a section view of the remote control device of **FIG. 2** taken along line a-a of **FIG. 2**;

[0019] **FIG. 2***b* is a perspective of an exemplary embodiment of ambulatory infusion device constructed in accordance with the present invention;

[0020] **FIG. 3** is a sectional side view of another exemplary embodiment of a remote control device constructed in accordance with the present invention;

[0021] **FIG. 3***a* is a sectional side view of another exemplary embodiment of an ambulatory infusion device constructed in accordance with the present invention;

[0022] **FIG. 4** is a chart illustrating voltage decay over a period of time and low battery level thresholds for a remote control device constructed in accordance with the present invention;

[0023] **FIG. 5** is a top plan view of a further exemplary embodiment of a remote control device constructed in accordance with the present invention;

[0024] **FIG. 5***a* is a sectional view of the remote control device of **FIG. 5** taken along line a-a of **FIG. 5**;

[0025] **FIG. 6** is a top plan view of a packaged assembly of a medical treatment apparatus assembled in accordance with the present invention;

[0026] **FIG. 6***a* is a top view of a remote control device of the packaged assembly of **FIG. 6**;

[0027] **FIG. 6***b* is a top view of a vial of liquid medication of the packaged assembly of **FIG. 6**; and

[0028] **FIGS. 7, 7***a* and **7***b* are perspective views illustrating an exemplary embodiment of a method of wireless communication according to the present invention conducted between a remote control device and a fluid delivery device of the present invention.

[0029] Like reference characters designate identical or corresponding components and units throughout the several views.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0030] Set forth hereinbelow are detailed descriptions of possible embodiments and examples of multi function remote control devices, medical treatment apparatus, and systems, kits and methods according to the present invention.

[0031] Referring first to **FIG. 1**, there is illustrated, generally at **100**, an exemplary embodiment of a multi function remote control device constructed in accordance with the

present invention. The remote control device **100** includes a visual display **110**, such as a liquid crystal display or LCD, that is mounted to a housing **102**. Preferably, the display **110** is a touch screen display such as that included in touch screen monitors found in various equipment including the Palm Pilot® personal digital assistant manufactured by Palm Inc. of Santa Clara Calif. Mounted to the housing **102** are electromechanical switches, such as a membrane keypad **120**, to allow the user to input data or activate commands. The remote control device **100** also includes means of transmitting electronic signals including antenna **130** which is shown external to the housing **102** but is preferably contained within the outer surface of the housing **102**. Examples of the internal electronics and other components of the device **100** are described in detail in subsequent sections. The wireless communication is accomplished using one or more forms of electronic information transfer including radio frequency, infrared or ultrasound communications, or other forms of non-wired electronic information transfer. The device receiving the communications would include a receiving antenna, and electronics to interpret and otherwise transform the communicated data to a useful form, such as that described in subsequent figures and embodiments found herebelow.

[**0032**] **FIG. 1***a* depicts an example of a medical treatment apparatus **1000** of the present invention. The example is a electrocardiogram device **1000** with multiple displays, a first medical treatment apparatus display **1010**A and a second medical treatment apparatus display **1010**B. The first display **1010**A is shown with waveforms produced by various EKG leads attached to a patient's skin (not shown) that make up a typical electrocardiogram of a heart patient with an inferior myocardial infarction. Other examples of medical treatment apparatus that can be remotely controlled include one or more of the following: external infusion pump, implanted infusion pump, pacemaker, cardiac defibrillator, neurostimulator, x-ray machine, EKG machine, diagnostic device, glucometer, blood analyzing equipment, electrocautery devices, operating room tables, visual monitors and laparoscopic remote control devices.

[**0033**] The medical treatment apparatus includes a housing **1002** on which is mounted various controls including electromechanical switches **1020**. Also depicted in **FIG. 1***a* is an integrated antenna **1030**, shown exposed but preferably contained within the device **1000**. The antenna **1030** receives signals from the remote control device **100** of **FIG. 1** so that a user can adjust various parameters, request information, or otherwise command, control or communicate with the medical treatment apparatus **1000**. In this embodiment, the parameters to be adjusted can include selection of a particular EKG lead to be displayed, adjustment of the display scale, or other parameters of the device **1000**, for example. This remote control capability may be of great advantage when the device **1000** is close to an active x-ray, contained in the sterile field of a medical procedure, or contained in other biologically hazardous fields, for example.

[**0034**] The medical treatment apparatus **1000** includes internal electronics (not shown) to take the information received via the antenna **1030**, interpret the data in electronic form, and adjust programming or other parameters accordingly. The remotely controllable apparatus **1000** can comprise medical devices and/or perform functions other than electrocardiogram monitoring, such as an external infusion pump, an implanted infusion pump, a pacemaker, an cardiac defibrillator, an neurostimulator, an x-ray machine, an EKG machine, blood sampling, blood analysis, a diagnostic device, a glucometer, blood analyzing equipment, an electrocautery device, an operating room table, a visual monitor, a laparoscopic device, and other medical equipment and functions.

[**0035**] In addition to receiving electronic wireless communication via the antenna **1030**, the medical treatment apparatus **1000** may also send wireless information back to the remote control device **1000**. The information can include diagnostic information, history information, equipment status information, alarm status information, or other information related to the function of the device **1000**. Information can also include device specific information, such as serial number, model number or a unique identifying alphanumeric code. Information can also include confirmation that a previously downloaded transmission from the remote control device **100** was properly received, or even improperly received, thereby triggering the remote control device **100** to repeat the previous transmission of electronic data.

[**0036**] Each transmission of electronic data between the device **100** and the apparatus **1000** can include an identification representing the remote control device **100**, the medical treatment apparatus **1000**, or both. The unique identifications, which can include codes, are placed in the electronic memory of either the remote control device **100** or the medical treatment apparatus **1000** during their manufacturing process. After an initial communication between the device **100** and the apparatus **1000**, either or both of the unique identifications can be transferred between the device and the apparatus, and all subsequent communications can include either or both of the unique identifications. In addition, prior to acting upon commands received from the remote control device **100**, a check of proper identification can eliminate the issue of a remote control device **100** communicating with the wrong medical treatment apparatus **1000**, and vice versa.

[**0037**] A start up or initial communication mode, therefore, is preferably conducted between the device **100** and the apparatus **1000** wherein either or both of the unique identifications is exchanged, followed by memory storage of either or both unique identifications. In addition, all subsequent communications preferably include a confirmation of the proper identification prior to acceptance of instructions. In some instances, the remote control device **100** may download a uniquely assigned identification to the medical treatment apparatus **1000**, which is then stored in the electronic memory of the medical treatment apparatus **1000** to establish a unique identification for that device. Examples of identification assignment, transfer, and confirmation are described in more detail in subsequent exemplary embodiments of the present invention.

[**0038**] It should be understood that the remote control device **100** may include software and electronic hardware for performing other functions, such that the remote control device **100** is a "multi-function" device. Other functions can include that of a personal digital assistant, such as the Palm Pilot®. Alternatively, the other functions of the remote control device **100** can include one or more of an electronic

game, a barcode reader, a television or VCR remote, or a cellular telephone, for example. Many other functions are possible.

[0039] **FIGS. 2 and 2***a* show another possible embodiment of a remote control device **100** according to the present invention. The remote control device is similar to the remote control device of **FIG. 1** such that similar elements have the same reference numerals. Internal components of the remote control device **100** are contained within a housing **102** and include a communication element **160** (referred to in appended claims as "remote" communication element) which is used to send wireless communication to the medical treatment apparatus **1000**. The wireless communication may consist of electronic packets of information sent by radio frequency, infrared, ultrasound or other wireless forms of communication. Also included is a power supply **108**, which can be integral to the device and rechargeable by attaching to a standard AC power converter. Alternatively, the power supply **108** may consist of standard battery technology such as nickel cadmium, alkaline, silver oxide or other batteries available at convenience and other stores, and be replaceable.

[0040] Within the housing **102** is an electronic printed circuit board **101** having electronics **105** that includes memory **107**, which is shown as a separate electronic module but preferably is integral with the electronics **205**. The electronics **105** also includes a microprocessor or other programmable and logic circuitry to perform programmable functions (referred to in the appended claims as "remote" processor). Other components of the electronics **105** can include digital circuitry, analog circuitry, resistors, capacitors, transistors, integrated circuits, amplifiers, additional microprocessors, logic circuitry, integrated circuits, programmable logic, analog to digital converters, digital to analog converters, multiplexors, and other semiconductor circuitry.

[0041] Preferably, a microprocessor and associated circuitry is embedded into the electronics **105** and receives programming signals from a membrane keypad **120**, controls the visual display **110**, and creates electronic command signals and identifiers to be broadcast in wireless form via the communication element **160**. Embedded in the memory **107** of the electronics **105** or included in the microprocessor is one or more microprocessor based software programs that define, control and facilitate the operation of the device **100** in a predetermined manner.

[0042] Combined with the memory **107**, which can be one or more components integrated into electronics **105**, can be fixed, preprogrammed read only memory and variable, read and writeable memory. The memory **107** includes the programming necessary to support all functions of the device **100**, including remote control of the medical treatment apparatus as well as the other functions such as cell phone operation, a personal digital assistant, a glucometer diagnostic function, a barcode reader, and an electronic game. The memory may also be used to store clinical therapy information, such as diabetes care guide, a troubleshooting guide and user manual for the medical treatment apparatus being remotely controlled, and a troubleshooting guide and user manual for the remote control device **100**.

[0043] Also included within the housing **102** is an alarm **106** mounted to the printed circuit board **101**. The alarm **106** preferably is an audio alarm such as a piezo buzzer, commercially available from Star Micronics Company, Ltd. of Edison, N.J. The alarm **106** is activated by the electronics **105** when an alert or alarm condition is encountered during operation of the remote control device **100**. Alarms may be predicated by a condition in the remote control device **100** or an alarm condition detected in the medical treatment apparatus **1000** that has been uploaded into the remote control device **100**. Examples of alarm conditions include detection of a malfunction, low battery conditions, or even an alarm clock function. Examples of alarm conditions uploaded from the medical treatment apparatus **1000** include low battery conditions, detection of malfunction, empty reservoir in a fluid delivery device, occlusion of flow in a fluid delivery device, out of paper condition, or out of communication range.

[0044] The communication element **160** is also shown mounted to the printed circuit board **101** and is electronically attached to the electronics **105** to feed the electronic signals, or packets of information, to and possibly from the communication element **160**. Also electrically connected to the printed circuit board **101** and the electronics **105** thereon is the user interface components **110**, **120**.

[0045] In one exemplary embodiment, a medical treatment apparatus of the present invention comprises an ambulatory fluid delivery device **10**, as shown in **FIG. 2***b*. The fluid delivery device **10** is for the infusion of insulin for diabetic patients, and an additional function of the remote control device **100** is a glucose measurement device, or glucometer function. In such an embodiment, the remote control device **100** includes the necessary hardware to measure blood glucose, such as that taken from a blood sample, so that a diabetic patient can avoid the need to carry multiple handheld devices (i.e., one for controlling the fluid delivery device and one for measuring blood glucose).

[0046] Thus, as shown in **FIG. 2**, the remote control device **100** includes a glucometer port **150**, which can comprise a standard wire connector, allowing attachment to an existing glucometer device, or a more sophisticated input device for measuring blood glucose utilizing optics or sensors for analyzing blood glucose strips or blood drops. Non-invasive blood glucose technologies are commercially available or in development by various manufacturers and developers. Cygnus Corporation of Redwood City, Calif., for example, manufacturers the Glucowatch Biographer blood glucose measuring system. The glucometer port **150** can be adapted to electronically connect with a device such as the Glucowatch to transmit and receiving blood glucose information. Alternatively, the information can be communicated via wireless technologies described herein utilizing communication element **160** and a transmitting or receiving element included in the glucometer.

[0047] Alternatively, the glucometer port **150** can be replaced with another input, output or combination input and output port for allowing attachment to other devices, performance of electro mechanical functions such as bar code scanning, attachment to an information upload or download device, or performance of another function. As shown in **FIG. 2***a*, the device **100** can also include a barcode reader port **140** for connecting to a standard barcode reader pen or gun (not shown) to simplify input of information such as drug type and concentration from a drug reservoir or vial.

Alternatively, the barcode reader port **140** may include the integrated bar code reading technology and avoid the need for another device. The device **100** also includes a computer port **170** for connection to a personal computer or other computer system to upload or download information, as well as offering temporary computer control of various functions including programming or program modification of the remote control device **100** itself. The computer port **170** can include integrated wireless communication technologies to connect to a separate computer or computer network without the need for wires or mechanical connection means.

[**0048**] Referring to **FIG. 2***b*, the fluid delivery device **10** is designed to be small and lightweight and includes a housing **20** and an adhesive attachment means (not shown) secured to an external bottom surface of the housing for attaching the device to the skin of a patient. Internal to the fluid delivery device **10** are a reservoir for storing the liquid medicament, a fluid dispenser for controlled fluid delivery, a communication element for receiving the wireless communications from the remote control device **100**, and electronics for receiving the electronic communication and controlling the function of the device. On the outer surface of the housing **20** is included a needle insertion septum **32** to allow fluid to be placed into the reservoir of the fluid delivery device **10** via a syringe. Alternatively, the fluid delivery device **10** may be prefilled with the liquid medication at a manufacturing site prior to the device **10** being distributed to the patient or caregiver, simplifying setup and reducing cost by eliminating patient filling and obviating the need for needle insertion septum **32**.

[**0049**] Exiting the housing **20** is the outlet of the fluid path of the device, including skin penetrating cannula **72**, which is inserted transcutaneously, or through the skin of a patient into the subcutaneous tissue or other transcutaneously accessed site, such as a vein or artery, intended for the fluid delivery. Alternatively, exiting the housing **20** may be a standard Luer attachment such that a connection to a standard transcutaneous infusion set can be made.

[**0050**] Preferably, the fluid delivery device **10** is designed to be low cost and have limited life such as 2 to 3 days and thereafter be disposable. Such an inexpensive, disposable device is possible because the device **10** does not have an expensive, complex user interface such as electromechanical switches and visual displays, since user interface is accomplished via the remote control device **100**.

[**0051**] The fluid delivery device **10** may be filled with insulin, and associated programming of fluid delivery device **10** and remote control device **100** sufficient to allow the sophisticated flow profiling and bolus requirements for a diabetic patient, such as insulin dependent or Type I diabetics. This patient population are required to take repeated doses of insulin just to survive, and the advantages of continuous infusion of insulin has been well demonstrated in scientific studies.

[**0052**] In the case where the remotely controlled medical treatment apparatus is a mass produced product, such as the disposable infusion pump **10** described above, the remote control device **100** may communicate with numerous infusion pumps **10** over a period of time. For each new infusion pump **10** placed into operation by a user, a unique identification of the fluid delivery device **10** can be uploaded into the remote control device **100** and a unique identification of the remote control device **100** can be downloaded into the fluid delivery device **10**.

[**0053**] In a preferred embodiment, the disposable fluid delivery device **10** does not include a unique identification, as this may add cost to the manufacturing process. Instead, at first communication with a new fluid delivery device **10**, the remote control device **100** is programmed to download a unique identification to the new fluid delivery device **10**, which in turn is programmed to store the unique identification in its internal memory for the remainder of its life. All subsequent communications between the remote control device **100** and the fluid delivery device **10** then include the unique identification previously downloaded to assure secure and proper communication between the remote control device **100** and the specific delivery device **10**.

[**0054**] For example, the memory **107** of the remote control device **100** automatically assigns a new, unique identification to each new pump **10** at the initial communication, and includes the unique identification in each communication with the pump to prevent the pump from receiving commands from other remote control devices that may be in proximity with the pump **10**. The initial communication and exchange of the unique identifications can be prompted by a user, or the remote control device **100** and the fluid delivery device **10** can be programmed to automatically exchange identifications upon initial communications.

[**0055**] **FIG. 3** depicts a cross sectional side view of another possible embodiment of a remote control device **100** of the present invention. The remote control device is similar to the remote control device of **FIG. 2** such that similar elements have the same reference numerals. The remote control device **100** of **FIG. 3**, however, further includes multiple power supplies to prevent inadvertent power outage for portions of the device **100** relating to control of a medical treatment apparatus.

[**0056**] Removable from the housing **102** is a battery door **111**, which allows access to first power supply **108**A and second power supply **108**B, which can comprise replaceable batteries. Preferably, at least one of the first power supply **108**A and the second power supply **108**B is always used to power each function of the remote control device **100**. When the energy remaining in the first power supply **108**A (referred to in the appended claims as "general purpose power supply") decreases to a certain predetermined level or other means of determining remaining energy life, the second power supply **108**B (referred to in the appended claims as "dedicated power supply") is utilized for power. The first power supply **108**A can continue to be depleted or may be electrically disconnected or otherwise unused. The second power supply **108**B is not used to supply power for each function, but a reduced number of functions including remote control of a medical treatment apparatus. Preferably, the second power supply **108**B provides power only to the remote control function.

[**0057**] Determination of remaining energy level for each power supply **108**A, **108**B can be performed by electronic voltage detectors, electronic current detectors and integration of values of current used, time duration measurements, measurements of types and duration of use, a combination of any of the aforementioned techniques along with other energy consumption and battery level detection methods

known to those of skill in the art. Power supply **108**A, **108**B selection based on power consumption management can be accomplished with electronic switches such as transistor or other semiconductors switching circuits.

[**0058**] It should be appreciated that the two power supplies **108**A, **108**B can provide power to separate specific functions, or there may be particular functions that are provided power by both power supplies. Particularly, the function of controlling a medical treatment apparatus can be powered by both power supplies **108**A, **108**B, while other functions are limited to just one of the two supplies **108**A, **108**B, for the purpose of insuring continued, non-interrupted remote control function. In a particular embodiment, the first power supply **108**A supplies power to all functions of the device **100**, and the second power supply **108**B only supplies power to the medical apparatus controlling functions and becomes activated only when the first power supply **108**A is depleted to a predetermined level. Each power supply **108**A, **108**B can be a battery, or other energy storage means such as a capacitor, can be user replaceable, or can be integral to the device and rechargeable with standard recharging means. In one possible embodiment, the second power supply is provided as a capacitor or battery that is not user replaceable, is enclosed within the housing **102**, and is not accessible via removal of a battery door.

[**0059**] In any event, the dual power supply configuration allows the remote control device **100** to prioritize providing power to support the remote control of a medical apparatus versus other user supportive functions, such as a cellular phone function. Since it may be greatly preferred to allow down time with the cellular function versus any down time with the control of the medical treatment apparatus, the dual power supply control functions described herein avoid a user inadvertently or accidentally depleting a battery supply using a function such as a phone call and then being unable to control their medical apparatus.

[**0060**] It is a great advantage for the user to be able to combine a remote control of a medical apparatus with other functions such as cellular phones, personal digital assistant, or other handheld electronic device. However, if use of the non-medical function depletes the battery to a low enough level to prevent control of the medical apparatus, the multi function device may lose its appeal. The power supply control circuitry described herein, therefore, prevents non-medical usage of remote control device **100** that would deplete the batteries to a point of loss of the medical apparatus remote control function.

[**0061**] **FIG. 3***a* shows a fluid delivery **10** to be remotely controlled by a remote control device **100** of the present invention. The fluid delivery device of **FIG. 3***a* is similar to the fluid delivery device of **FIG. 2***b*. The fluid delivery device **10** includes recessed housing **200** which includes a recessed surface **29** positioned within a continuous ring adhesive layer **201**. Located beneath housing adhesive layer **201** may be secondary housing adhesive layer **202** such that if the housing adhesive layer **201** loses sufficient adhesive properties and is removed, the secondary adhesive layer **202** is available to attach, or reattach, the fluid delivery device **10** to skin of a patient. Preferably, the size of the fluid delivery device **10** is small to allow comfortable adhesive attachment to the patient's skin. Based on the size and shape of recessed housing **200** it may be desirable for the outer shell to flex after adhesive attachment to the patient's skin. Included at various locations along recessed housing **200** are housing hinged sections **23**, to allow flexing.

[**0062**] Included within the housing **200** is a reservoir **30** which is designed and constructed to be compatible with the liquid medication, such as insulin, to be infused. In a preferred embodiment, the reservoir **30** is prefilled with the liquid medication, however the entire reservoir can be inserted by the user if in the form of a prefilled cartridge, not shown, or the fluid delivery device **10** may include medication fill means, such as a needle penetrable septum in fluid communication with the reservoir **30**, also not shown. The reservoir **30** is in fluid communication with a dispenser **40**, which is used to precisely control the amount of fluid to exit the fluid delivery device **10** via exit port assembly **70**. **FIG. 3***a* depicts an exit port assembly **70** including a standard attachment such as a Luer connector **71** which can be attached to a transcutaneous infusion set (not shown) for transcutaneous delivery of the liquid medication. Alternatively, the Luer connector **71** can be replaced with a transcutaneous cannula assembly that is integrated into exit port assembly **70** and obviates the need for the transcutaneous infusion set.

[**0063**] The dispenser **40** controls fluid flow from the reservoir **30** to the exit port assembly **70**, and can comprise a linear or rotary peristaltic pump if the reservoir **30** is not pressurized. Alternatively, the dispenser **40** can comprise an electrodynamic pump, a displacement pump or other fluid pumping mechanism. The dispenser **40** can be combined with a separate metering element to achieve the proper volume of fluid to be infused, or the dispenser **40** can be adapted to independently infuse the correct volumes.

[**0064**] If the reservoir **30** is pressurized, by a compressing member or by being enclosed in a gas pressurized chamber for example, the dispenser **40** can be adapted to simply meter the fluid from the reservoir. The dispenser **40** can then include an accumulator chamber and valves before and after the accumulator chamber to dispense fixed pulses of fluid. Alternatively, the dispenser **40** can be adapted to control flow rate via orifice constriction and expansion.

[**0065**] Still referring to **FIG. 3***a*, an electronic microcontroller **50** (referred to in the appended claims as a "local" processor) is used to electronically control the dispenser **40**. The dispenser **40** can include electrically driven propulsion means, electrically activated remote control devices such as piezo valves or solenoid actuators, motors or micro motors, or other electromechanical components requiring electrical signals for activation, power or both. Powering the dispenser **40** and the electronic microcontroller **50** is a power supply **80**, which is preferably a battery. If the fluid delivery device **10** is a low cost disposable advice, the power supply **80** is preferably integral to the fluid delivery device **10** to thereby avoid the need for a user to purchase and insert batteries.

[**0066**] The fluid delivery device **10** of **FIG. 3***a* is controlled by a remote control device, such as the remote control devices **100** of **FIGS. 2 and 3**, via wireless electronic signals sent by the remote control device and received by a communication element **60** (referred to in the appended claims as a "local" communication element), shown in **FIG. 3***a*. Preferably, the fluid delivery device **10** is a low cost disposable insulin pump, and includes no user interface components and can only be interfaced with by a user via a remote control device.

[0067] In one embodiment, the communication element **60** both receives and transmits electronic signals to the remote control device **100**. Information transmitted by the fluid delivery device **10** may include alarm conditions, programming history, infusion history, confirmation of programming, handshaking or other communication confirming codes, or other electronic controls or information transfer. Information can be transferred with standard wireless technologies such as radio frequency or infrared, and include standard handshaking or other communication confirmation protocols such as those employed in commercially available modems and fax machines.

[0068] **FIG. 4** is a graph of voltage versus time of a power supply for a handheld electronic device. The decay curves of voltage over time for typical use or typical battery drain is shown. Referring also to **FIG. 3**, such measurements of the general purpose power supply **108**A can be used to by the remote control device **100** to determine when the dedicated power supply **108**B is used to supply power to the remote control device **100**. For example, the internal electronics **105** can measure the energy level, such as a voltage level, of the first power supply **108**A and when the level decreases below a certain value, employ the second power supply **108**B.

[0069] In **FIG. 4**, the voltage curve is for the general purpose power supply **108**A of **FIG. 3**. A second voltage threshold VT**2** is shown in **FIG. 4** and represents a predetermined energy level at which the dedicated power supply **108**B is utilized. The measurement electronics **105** may include means of detecting when the voltage of the general purpose power supply **108**A first drops below the second voltage threshold VT**2**, such that if the voltage increases above the second voltage threshold VT**2** thereafter, the battery control conditions remain unchanged so that the dedicated power supply **108**B remains connected. Such a method of differentiating a voltage level slightly above a threshold if the level had previously decreased below the threshold is known as a hysteresis function or method. Once a threshold level is crossed, minor measurement perturbations above the threshold do not change the resulting actions from the initial crossing. When the voltage exceeds the threshold by a more significant, preset level, such as that caused by new battery replacement or recharge, the actions are reversed or a new action performed.

[0070] An alternative to the dual power supply construction presented in **FIG. 3** and discussed above, includes the creation of two preset energy thresholds for use with the single power supply **108** illustrated in **FIG. 2***a*. The remote control device **100** further includes means for measuring a threshold such as a first voltage threshold VT**1**, illustrated in **FIG. 4**. When the energy level in the single power supply **108** decreases to below the first voltage threshold VT**1**, functions of the device **100** not related to the remote control of the medical treatment apparatus are deactivated or shutdown.

[0071] For example, a non-medical function such as cellular telephone use, may be of a de-prioritized nature as compared to control of a medical treatment apparatus such as a fluid delivery device for the delivery of insulin to a diabetic patient. Therefore, the remote processor **105** is programmed to shut down the cellular telephone function of the remote control device **100** when the available power of the single power supply **108** decreases below the first voltage threshold VT**1** in order to allow one or more hours of control of the fluid delivery device.

[0072] In addition, a possible embodiment of the remote control device **100** can include an override function that allows continued use of the non-medical control function(s) if desired by a user. In cases of emergency, for example, the cellular phone function of the device **100** may be of such importance that continued use of the phone function at the risk of deactivation of the medical control function due to depletion of the single power supply **108** may be acceptable. In such an embodiment, the remote control device **100** might require the user to override the deactivation by confirmation via the keyboard **120** or other user input means of the device **100** to reactivate the phone function. The override may be temporary or permanent, and may trigger a second level of remaining energy level thresholds (e.g., VT**2**) to be employed for the deactivation of the phone function when the available power of the single power supply **108** decreases below the second voltage threshold VT**2**.

[0073] The remote control device **100** may include means of alerting the user prior to deactivation of any functions. This alert may be accomplished with audio or visual information made available to the user by detection of particular energy states of the one or more power supplies. For example, a voltage threshold just above the first voltage threshold VT**1** may cause the alert condition to occur, thus notifying the user that certain functions are near deactivation, similar to a low battery warning condition found in many battery powered devices. In addition, multiple thresholds can be detectable by the electronics of the remote control device **100** such that one or more low battery conditions, as they relate to individual or groups of specific functions, can be used to selectively deactivate individual or groups of specific functions in a prioritized manner. For example, a remote control device **100** that includes medical treatment apparatus control, cellular telephone function and personal digital assistant function, may include thresholds for all three stated functions and deactivate the PDA function first and then the cellular function prior to the medical treatment apparatus remote control device function.

[0074] It should be considered in the scope of this application that there are various techniques for determining the amount of energy remaining in one or more power supplies. Voltage detection is common and the energy dissipation curves of batteries of various technologies can be predicted quite reliably. Other techniques can be used in conjunction with or independent of voltage detection without departing from the spirit of this application. Examples of one or two power supply embodiments have been described, however three or more power supplies can be used to achieve similar outcomes, and a single power supply may consist of more than one battery, connected in series or in parallel or both. In addition, multiple energy thresholds can be measured in any or all of the power supplies to change the status of function availability. In other words, one or more batteries can be employed utilizing one or more remaining energy measurements, preferably voltage thresholds. Based on these thresholds, additional power supplies can be brought on line and or particular functions made no longer available or deactivated, to insure continued operation of the medical apparatus apparatus control function.

[0075] In addition to discreet energy level measurements, such as voltage level measurements, a history of activity

potentially including current measurements, history of battery replacements and measurements, and other multiple information data analysis can be used, integrated, or otherwise analyzed to determine which functions to enable and disable, or how to distribute power among the functions.

[0076] Another exemplary embodiment of a remote control device **100** of the present invention is shown in **FIGS. 5 and 5***a*. The device of **FIGS. 5 and 5***a* is similar to the device of **FIGS. 2 and 2***a* such that similar elements have the same reference numerals. The device of **FIGS. 5 and 5***a*, however, includes a "touch screen" display **110**TS for allowing user input as well as for displaying information.

[0077] Also included in the remote control device **100** of **FIGS. 5 and 5***a* is an electronic communication port **171**. The port **171** can be a simple modem for connection to an outside computer or internet system via a phone line, or an Ethernet connector for connection to a network, the internet, or other wired electronic communication channel. The communication port **171** can facilitate other forms of electronic information upload or download, most particularly information which can be sent to the user to help manage, troubleshoot and otherwise use the medical treatment apparatus being controlled. The information can be uploaded or downloaded from a clinician or other health care giver, the manufacturer of the remote control device **100**, or the manufacturer of the medical treatment apparatus being remotely cointrolled.

[0078] Alternatively, all of these upload and download communications can be accomplished via wireless technologies accepted by communication element **160** contained within the remote control device **100**. In this wireless scenario, communication can be sent via satellite or other global or near global communication, updating each applicable remote control device **100** with new programming information, text or user manual information, or other data stored within the memory **107**. The information can be received by communication element **160** whose primary function is to send, and potentially receive wireless communications to medical apparatus treatment apparatus **1000**.

[0079] **FIG. 6** shows a packaged assembly **350** which includes a fluid delivery device **10** similar to the fluid delivery devices of **FIGS. 2***b* and **3***a*. The fluid delivery device **10** is packaged in an assembly tray **353**, which can be constructed of a sterilizable material such as PETG, or polycarbonate, and is seal with an assembly lid **352**, which can be constructed of sterilizable material such as Tyvek® wrap material supplied by DuPont Corporation of Wilmington, Del. The assembly lid **352** may include an adhesive on its bottom surface to facilitate sealed attachment to the assembly tray **353**.

[0080] The sealed tray construction allows the fluid delivery device **10** to be sterilized utilizing various methods, including ethylene oxide sterilization. In one possible embodiment, the fluid delivery device **10** of the packaged assembly **350** can include an integral transcutaneous infusion set. At least the transcutaneous infusion set and fluid path portions of the device **10** are sterilized to prevent contaminants from passing through the skin of a patient using the device **10**.

[0081] Also shown in **FIG. 6**, the fluid delivery device **10** is provided with an information barcode **26**. Such an information barcode **26** may be utilized by various systems for cataloging or otherwise recording information about the fluid delivery device **10**. The remote control device **100** of **FIG. 6***a* can be provided with a bar code reader function, and can be programmed to upload the information barcode **26** data to perform an initialization function described hereabove. The information barcode **26** data can be unique for each fluid delivery device **10** and include a unique fluid delivery device identification, or other unique and non-unique information such as manufacturing date, serial number, type of medication preloaded, concentration of medication, physician identification, patient identification, or other clinical or non-clinical information. The use of information barcode **26** containing unique device information, versus including such unique information in the electronic memory of the fluid delivery device **10** may be more efficient and cost effective for mass production of the fluid delivery device **10**, especially in designs and constructions where the device is to be of extreme low cost for limited life or disposable use.

[0082] A preferred packaging construction to the tray and lid described above would be a sealable pouch, common to the medical apparatus industry. The pouches usually consist of a rectangular piece of breathable material such as Tyvek, which is sealed to a piece of clear flexible plastic, such as thin Mylar. The pouch construction can be sterilized in similar fashion to the tray and lid packaging, and is generally of less cost to manufacture without providing the rigid protection of the tray packaging.

[0083] **FIG. 6***b* depicts a top view of therapeutic fluid supply **250**. Therapeutic fluid supply **250** may include a glass or plastic vial, and may be filled with various types of one or more liquid medications such as insulin. The therapeutic fluid supply **250** may be loaded, like a cartridge, into a properly designed and adapted fluid delivery device **10**, or the contents of therapeutic fluid supply **250** may be transferred, through interlocking fluid connection or via syringe and needle, into fluid delivery device **10** at a integral injection port, not shown. Alternatively, fluid delivery device **10** may be prefilled with the liquid medication obviating the need for therapeutic fluid supply **250**.

[0084] Various ways of combining devices of the present invention into appropriate infusion kits can include packaging multiple units of one type of device with a single other type of device. For example, a single remote control device **100** of the present invention can be provided as a kit with thirty to one hundred low cost, disposable fluid delivery devices **10** of the present invention. Typical kit configurations include a single remote control device **100** packaged with multiple delivery device packaged assemblies **350**, each containing fluid delivery device **10**. If the fluid delivery device **10** is not filled with liquid medication, therapeutic fluid supply **250** are also packaged in the infusion kit. In addition to the above components or products, other components or products may be packaged in the infusion kit such as user instructions, batteries for the remote control device **100**, multiple batteries for the fluid delivery devices **10**, syringes, needles, transcutaneous penetration site preparation materials, and other peripheral devices. In addition, blood glucose measuring supplies such as finger prick devices, test strips, diagnostic devices such as glucometers, and other blood glucose measurement accessory devices may be supplied in the kit. One or more backup remote

control devices **100** can also be included with the kit. Many variations of kits are possible.

[**0085**] **FIGS. 7, 7***a* and **7***b* depict diagrammatic views of an embodiment of a remote control device **100** communicating with an embodiment of a fluid delivery device **10** or the present invention. **FIG. 7** depicts an initial communication between the remote control device **100** and the fluid delivery device **10** wherein the remote control device **100** sends a wireless electronic information signal to the fluid delivery device **10**. The internal electronics of the fluid delivery device are programmed to detect an initial communication, and from then on only accept communications that include information different than information contained in the initial communication. The initial communication may include codes that signify the initiation, and subsequent communications may include codes that not only signify not being the initial communication, but also include information calculated, uploaded, downloaded or otherwise determined during or as a result of the initial communication.

[**0086**] In a preferred embodiment, all fluid delivery device **10** internal programming by manufacturing is standardized, or non-unique, to reduce manufacturing costs. At the initial communication with the remote control device **100**, a unique identification is transmitted to the fluid delivery device **10**, received by the fluid delivery device **10**, and stored in the memory of the fluid delivery device **10**. In a preferred embodiment, the fluid delivery device **10** can transmit signals as well as receive, to provide two-way communication with the remote control device. Receipt of the assigned fluid delivery device identification can be transmitted by the fluid delivery device **10** to the remote control device **100** to confirm the initialization and subsequent communications.

[**0087**] The remote control device **100** memory may communicate with many fluid delivery device **10** over the life of the remote control device **100**, and thus a matrix of fluid delivery device identifications would be maintained in the memory of the remote control device **100** to avoid duplication of identifications. In addition, the remote control device **100** may transmit a unique identification for itself to the fluid delivery device **10**, to insure that in all subsequent communications, signals are received by the correct remote control device. For practical purposed, the unique identification downloaded to the fluid delivery device **10** may include a unique prefix, suffix or other part identifying the remote control device in a unique way, as well as a unique additional identification code, whereby the combined codes is the unique identification for the fluid delivery device, and the entire unique code is checked at each transmission to insure proper correlation of both devices. In the preferred embodiment in which the fluid delivery device **10** can transmit information to the remote control device, the unique identification can be included in fluid delivery device **10** transmitted communications as well.

[**0088**] In an alternative embodiment, the fluid delivery device **10** may be manufactured with a unique identification, such as a serial number, in its electronic memory. In this configuration, the fluid delivery device **10** would transmit the unique identification to the remote control device **100** in the initial communication in addition to the remote control device **100** transmitting its unique identification to the fluid delivery device **10**, each device holding both unique codes in electronic memory, and checking for proper device communication at each transmission.

[**0089**] **FIG. 7** depicts the initial communication between devices where a remote control device identification "RCID", and a fluid delivery device identification "FDDID" are transmitted from remote control device **100** to the fluid delivery device **10**. As described hereabove, the unique identification can simply be a combination of the two device identifications with or without additional coded information. The fluid delivery device identification FDDID can be generated by the remote control device **100** or already preprogrammed into fluid delivery device **10** at the time of manufacturing. In this instance, the code may be included in random access or RAM memory or in read only memory or ROM memory. In the case where the unique identification is downloaded from the remote control device **100**, the unique identification would be stored in RAM. Alternatively, a label containing a barcode, as described hereabove, can be read by the remote control device **100** and subsequently downloaded into the electronic memory of the fluid delivery device **10**.

[**0090**] **FIG. 7***b* depicts a subsequent electronic, wireless communication including the remote control device identification RCID and including the fluid delivery device identification FDDID in addition to other programming, control, command or other information sent from the remote control device **100** to fluid delivery device **10**. Prior to action related to the command codes sent, a check would be performed to confirm completion and accuracy of the message, using checksum or other appropriate techniques, as well as a check that the proper remote control device **100** had sent the information to the proper fluid delivery device **10**. After acceptable confirmations, a return signal may be sent to acknowledge acceptance, and then appropriate actions would take place in the fluid delivery device **10**.

[**0091**] **FIG. 7***c* depicts a subsequent electronic, wireless communication including the remote control device identification RCID and including the fluid delivery device identification FDDID in addition to other programming, control, command or other information sent from the fluid delivery device **10** to remote control device **100**. Prior to action related to the command codes sent, a check would be performed to confirm completion and accuracy of the message, using checksum or other techniques known to those of skill in the art, as well as a check that the proper fluid delivery device **10** had sent the information to the proper remote control device **100**. After acceptable confirmations, a return signal may be sent to acknowledge acceptance, and then appropriate actions would take place in the remote control device **100**.

[**0092**] In a preferred embodiment, the fluid delivery device **10** is an insulin delivery device for diabetic patients. The fluid delivery device is disposable, used by the patient for three or less days, and requires the remote control device **100** for programming and use. It is imperative that proper communications are confirmed including confirmation that the proper remote control device **100** is commanding the proper fluid delivery device **10**. These patients may be part of patient groups, attend diabetes conferences, or otherwise be in the presence of one or multiple patients who utilize the same system. Protocols such as that disclosed in this application are imperative to prevent undesired programming changes of any type. In addition, the remote control device

100 and or fluid delivery device **10** may include a proximity alarm or alarms such that when the distance between the remote control device **100** and fluid delivery device **10** exceeds a particular amount, one or both devices produce an audible and or tactile, such as vibrational, alarm.

[**0093**] The unique identification of either device may include alpha numeric designators or simple binary digits, or a binary representation of a more sophisticated code. The transmissions may include digital or more sophisticated waveforms, each including the unique codes representing either or both the medical treatment apparatus devices. The fluid delivery device **10** programming can be made such that after the initial communication with a remote control device **100**, the fluid delivery device will only accept command codes from transmissions received with that remote control device **100** unique identification, remote control device identification RCCID. Alternatively, the fluid delivery device **10** programming may allow control from multiple remote control device **100**, with more complex acceptance schemes. The remote control device **100** may include programming and unique identifications that identify master remote control devices, or remote control devices that are used for diagnostic, troubleshooting, clinician, or other purposes. Control of a fluid delivery device **10** by a remote control device **100** that did not initialize that particular fluid delivery device **10** may involve special passwords, keys, or other special functions or actions to allow the fluid delivery device **10** to accept the commands from the new remote control device **100**. Conversely, the remote control device **100** will include programming to allow it to communicate with many fluid delivery device **10**, however, perhaps not more than one at a time. The remote control device **100** may include programming such that after an initial communication, only that particular fluid delivery device **10** can be controlled until another initial communication information transfer is performed with a new fluid delivery device **10**, after which the previous fluid delivery device **10** may or may not be able to be controlled by that remote control device **100**. Obviously, it may be desirable to obtain information from a previously used fluid delivery device **10**, so programming may allow information transfer, or upload from the previously used fluid delivery device **10** to the remote control device **100** but prevent actual infusion programming or other controls.

[**0094**] The remote control device may include programming or command sets which are available only to certain users such as the patient, clinician, diagnostic technician, clinical technician, product technician, or other unique user. Each of the functions may be password or otherwise controlled to limit access. In all instances, the remote control device **100** will include at least a transmitter, and a medical treatment apparatus, such as the fluid delivery device **10**, will include at least a receiver. In a preferred embodiment, remote control device **100** further includes a receiver, and the fluid delivery device **10**, further includes a transmitter.

[**0095**] Various methods of using remote control device **100** are included in the present invention and described above. The method of programming the fluid delivery device **10** with remote programmer **100** as well as control of other forms of medical treatment apparatus **1000** are described. Also relevant is the ability to update the internal programming of either the fluid delivery device **10** or the remote control device **100** by the corresponding device. Methods of creating and mapping unique alphanumeric identifications for a medical treatment apparatus, such as the fluid delivery device **10** of the present invention, and the remote control device **100** have been described.

[**0096**] While the majority of description for a medical treatment apparatus have regarded a fluid delivery device **10**, many other types of medical apparatuses are applicable for use with a remote control device of the present invention **100**. The value of the multi function remote control **100** is enhanced in situations where the user is more likely to carry the remote control device in their daily routine, or as part of their job. This condition is obvious with the diabetic patient for continuous infusion of insulin, but also found in patients and hospital workers who need to control medical treatment apparatus for a long portion of their day, potentially their working day. The advantage of other multiple uses makes the requirement of carrying and otherwise maintaining the remote control device seem less burdensome, and may reduce the need to carry around a separate device such as a PDA, cellular phone or other handheld electronic device. The methods and design features described in this application that relate to disposable fluid delivery devices, can be applied to non-disposable fluid delivery devices as well as other medical apparatus and should not in any way limit the scope of the remote control device **100** or the applicable systems.

[**0097**] Although exemplary embodiments of the invention have been shown and described, many changes, modifications and substitutions may be made by those having ordinary skill in the art without necessarily departing from the spirit and scope of this invention. For example, a power supply has often been described as a battery, such as a silver oxide battery. If two or more silver oxide batteries were connected in series to increase voltage or if placed in parallel to increase the available supply of current, they may be considered as a single power supply. Combinations of batteries, capacitors and other energy storage devices in series or parallel, acting either as a single power supply or as multiple power supplies can be made without departing from the scope of this application. Also, various means of power or energy level detection have been described, such as voltage level detection, but various other means of measuring, monitoring or otherwise calculating remaining energy can be used. Also, various methods of creating and storing electronic unique identifying codes have been described, however other means of coding transmissions to create unique identifications that can be uploaded and downloaded to accomplish confirmed communication between the remote control device **100** and medical treatment apparatus **1000** may be employed.

[**0098**] Also, the fluid delivery device of this invention is intended to be low cost, light weight, simple to use and potentially disposable by removing a majority of the user interface, including electromechanical switches, from the fluid delivery device, and including a separate remote control device to replace those functions. A reservoir, fluid dispenser, transcutaneous fluid administration means, solid state electronics and wireless communications are included in the fluid delivery device to perform its intended function. While various means of reservoir construction, pressurization means, fluid pumping means, fluid metering means, transcutaneous delivery, electronic control and wireless communications have been discussed in this application,

alternatives to each of these areas can be made without departing from the spirit of the invention.

[0099] In addition, where this patent application has listed the steps of a method or procedure in a specific order, it may be possible (or even expedient in certain circumstances) to change the order in which some steps are performed, and it is intended that the particular steps of the method or procedure claims set forth herebelow not be construed as being order-specific unless such order specificity is expressly stated in the claim.

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36. A system for providing medical treatment to a patient, comprising:

A) a medical treatment apparatus including,

a local processor, and

a local communication element connected to the local processor;

B) a remote control device separate from the medical treatment apparatus and including,

a remote processor,

user interface components connected to the remote processor,

a remote communication element connected to the remote processor and adapted to communicate with the local communication element of the medical treatment apparatus in a wireless manner such that information can be transferred between the local processor and the remote processor, and

a power supply connected to the remote processor, wherein the remote processor is programmed to only conduct functions related to the transfer of information between the local processor and the remote processor upon a measured power level of the power supply falling below a predetermined minimum power level;

wherein the medical treatment apparatus comprises a fluid delivery device; and the remote control device further comprises a glucometer.

37. A system according to claim 36, wherein the power supply comprises a battery.

38. A system according to claim 36, wherein the power supply is user-replaceable.

39. A system according to claim 36, wherein the remote control device further includes an alarm connected to the remote processor and the remote processor is programmed to activate the alarm upon the measured power level of the power supply falling below the predetermined minimum power level.

40. A system according to claim 39, wherein the alarm comprises an audible alarm.

41. A system according to claim 36, wherein the remote processor is programmed to ignore hysteresis in the measured power level.

42. A system according to claim 36, wherein the medical treatment apparatus includes a unique identification included in all communications between the medical treatment apparatus and the remote control device.

43. A system according to claim 36, wherein the remote processor is programmed to receive a unique identification for the medical treatment apparatus during a first communication with the medical treatment apparatus.

44. A system according to claim 43, wherein all subsequent communications between the medical treatment apparatus and the remote control device include the unique identification for the medical treatment apparatus.

45. A system according to claim 36, wherein the remote processor is programmed to send a unique identification for the remote control device during a first communication with the medical treatment apparatus.

46. A system according to claim 45, wherein all subsequent communications between the medical treatment apparatus and the remote control device includes the unique identification for the remote control device.

47. A system according to claim 36, wherein the remote control device includes a unique identification included in all communications between the medical treatment apparatus and the remote control device.

48. (Canceled)

49. A system according to claim 36, wherein the medical treatment apparatus comprises a fluid delivery device also including:

an exit port assembly, and

a dispenser for causing fluid from a reservoir to flow to the exit port assembly,

wherein the local processor is connected to the dispenser and is programmed to cause fluid flow to the exit port assembly based upon flow instructions.

50. A system according to claim 49, wherein the exit port assembly of the fluid delivery device includes a transcutaneous access tool.

51. A system according to claim 49, wherein the local processor is programmed to cause fluid flow to the exit port assembly only upon receiving the flow instructions from the remote control device.

52. A system according to claim 49, wherein the fluid delivery device further comprises a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly.

53. A system according to claim 52, wherein the reservoir contains a therapeutic fluid.

54. A system according to claim 53, wherein the fluid comprises insulin.

55. A system according to claim 52, wherein the fluid delivery device further comprises a fill port connected to the reservoir.

56. A system according to claim 49, wherein:

the local processor of the fluid delivery device is programmed to cause a flow of fluid to the exit port assembly based solely on flow instructions from the separate, remote control device;

the local communication unit includes a wireless receiver for receiving the flow instructions and delivering the flow instructions to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

57. A system according to claim 56, wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the wireless receiver, and wherein the housing is free of user input components for providing the flow instructions to the local processor.

58. A system according to claim 49, wherein:

the local processor of the fluid delivery device is programmed to provide flow information;

the local communication unit includes a wireless transmitter for transmitting the flow information from the local processor;

the remote communication unit of the remote control device includes a remote receiver for receiving the flow information from the local transmitter; and

the user interface components of the remote control device include output components connected to the remote processor for allowing a user to receive the flow information.

59. A system according to claim 58, wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the local communication unit, and wherein the housing is free of user output components for providing the flow information from the local processor to a user.

60. A system according to claim 59, wherein:

the local processor is programmed to receive at least some of the flow instructions from the remote control unit;

the local communication unit also includes a wireless receiver connected to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

61. A kit including a system according to claim 49, and further comprising a subcutaneous access tool for connection to the exit port assembly of the fluid delivery device.

62. A kit according to claim 61, including one of the remote control device, a plurality of the fluid delivery devices, and a plurality of subcutaneous access tools for connection to the exit ports of the fluid delivery device.

63. A kit according to claim 62, wherein each fluid delivery device includes a bar code.

64. A system according to claim 49, wherein the fluid delivery device is packaged in a container for shipping and handling prior to use.

65. A system according to claim 36, wherein the remote control device is also adapted to function as at least one of a cellular phone, a personal digital assistant, and an electronic game.

66. A system according to claim 36, wherein the remote control device further includes electronic memory storing a user manual for the medical treatment apparatus.

67. A system according to claim 36, wherein the wireless communication between the remote control device and the medical treatment apparatus is radio frequency signals.

68. A system for providing medical treatment to a patient, comprising:

A) a medical treatment apparatus including,

a local processor, and

a local communication element connected to the local processor;

B) a remote control device separate from the medical treatment apparatus and including,

a remote processor,

user interface components connected to the remote processor, and

a remote communication element connected to the remote processor and adapted to communicate with the local communication element of the medical treatment apparatus in a wireless manner such that information can be transferred between the local processor and the remote processor;

wherein at least one of the remote control device and the medical treatment apparatus includes a unique identification included in at least one communication between the medical treatment apparatus and the remote control device.

69. A system according to claim 68, wherein each of the remote control device and the medical treatment apparatus includes a unique identification.

70. A system according to claim 68, wherein the unique identification is included in all communications between the medical treatment apparatus and the remote control device.

71. A system according to claim 68, wherein the remote processor is programmed to receive a unique identification for the medical treatment apparatus during a first communication with the medical treatment apparatus.

72. A system according to claim 68, wherein the remote processor is programmed to send a unique identification for the remote control device during a first communication with the medical treatment apparatus.

73. A system according to claim 72, wherein the local processor is programmed to thereafter accept commands only from the remote control device associated with the unique identification.

74. A system according to claim 68, wherein the medical treatment apparatus comprises one of an external infusion pump, an implanted infusion pump, a pacemaker, a cardiac defibrillator, a neurostimulator, an x-ray machine, an EKG machine, a diagnostic device, a glucometer, a blood analyzer, an electrocautery device, an operating room table, a monitor, and a laparoscopic controller.

75. A system according to claim 68, wherein the medical treatment apparatus comprises a fluid delivery device also including:

an exit port assembly, and

a dispenser for causing fluid from a reservoir to flow to the exit port assembly,

wherein the local processor is connected to the dispenser and is programmed to cause fluid flow to the exit port assembly based upon flow instructions.

76. A system according to claim 75, wherein the exit port assembly of the fluid delivery device includes a transcutaneous access tool.

77. A system according to claim 75, wherein the local processor is programmed to cause fluid flow to the exit port assembly only upon receiving the flow instructions from the remote control device.

78. A system according to claim 75, wherein the fluid delivery device further comprises a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly.

79. A system according to claim 78, wherein the reservoir contains a therapeutic fluid.

80. A system according to claim 79, wherein the fluid comprises insulin.

81. A system according to claim 78, wherein the fluid delivery device further comprises a fill port connected to the reservoir.

82. A system according to claim 75, wherein:

the local processor of the fluid delivery device is programmed to cause a flow of fluid to the exit port assembly based solely on flow instructions from the separate, remote control device;

the local communication unit includes a wireless receiver for receiving the flow instructions and delivering the flow instructions to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

83. A system according to claim 82, wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the wireless receiver, and wherein the housing is free of user input components for providing the flow instructions to the local processor.

84. A system according to claim 75, wherein:

the local processor of the fluid delivery device is programmed to provide flow information;

the local communication unit includes a wireless transmitter for transmitting the flow information from the local processor;

the remote communication unit of the remote control device includes a remote receiver for receiving the flow information from the local transmitter; and

the user interface components of the remote control device include output components connected to the remote processor for allowing a user to receive the flow information.

85. A system according to claim 84, wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the local communication unit, and wherein the housing is free of user output components for providing the flow information from the local processor to a user.

86. A system according to claim 84, wherein:

the local processor is programmed to receive at least some of the flow instructions from the remote control unit;

the local communication unit also includes a wireless receiver connected to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

87. A kit including a system according to claim 75, and further comprising a subcutaneous access tool for connection to the exit port assembly of the fluid delivery device.

88. A kit according to claim 87, including one of the remote control device, a plurality of the fluid delivery devices, and a plurality of subcutaneous access tools for connection to the exit ports of the fluid delivery device.

89. A kit according to claim 88, wherein each fluid delivery device includes a bar code.

90. A system according to claim 75, wherein the fluid delivery device is packaged in a container for shipping and handling prior to use.

91. A system according to claim 68, wherein the remote control device is also adapted to function as at least one of

a cellular phone, a personal digital assistant, and an electronic game.

92. A system according to claim 68, wherein the remote control device further includes electronic memory storing a user manual for the medical treatment apparatus.

93. A system according to claim 68, wherein the wireless communication between the remote control device and the medical treatment apparatus is radio frequency signals.

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